ISO/IEC 17025:1999 versus 2005

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ISO/IEC 17025:1999 versus 2005

- The First Edition of ISO/IEC 17025 was released in **1999;**
- The following year ***ISO 9001:2000*** – ***Quality Management Systems*** – ***Requirements*** was released.

ISO/IEC 17025:1999 versus 2005

- The **First Edition (1999) of 17025** referenced the predecessors of ISO 9001:2000; namely ISO 9001:1994 and ISO 9002:1994;
- Once the 2000 version of ISO 9001 was released, it became obvious that the **First Edition of 17025** would have to be revised to reflect the latest version of ISO 9001.

ISO/IEC 17025:1999 versus 2005

- The **Second Edition of 17025** was released in 2005 and its clauses reflect the material carried in ISO 9001:2000.
- The **Second Edition** is considered to be a technical revision and it replaces the First Edition in its entirety.
- The International Laboratory Accreditation Cooperation (ILAC) has set **a transition period of two years** from the date of publication of the new edition – **12 May 2005** – for accredited laboratories to comply with the new standard's requirements.

ISO/IEC 17025:1999 versus 2005

- **Both editions of 17025 rely heavily on the earlier versions of the standard; namely ISO/IEC Guide 25 and EN 45001.**
- The standard contains all the requirements necessary for a calibration or a testing laboratory to show competence in its testing area.
- It contains both management and technical requirements and it is an essential piece of the complete program to verify a laboratory's competence.

What's new in 17025:2005

- **Changes for the sake of clarification; that is, editorial changes that are not considered additional requirements**
  - **No action required by labs or assessors**

- **A number of additions to requirements including a new and separate clause on 'Improvement'**
  - **Action required by labs and assessors**

Changes in the Table of Contents

- **In comparing the two Tables of Contents, three key changes can be seen:**
  - 4.2 Management System (used to be Quality System)
  - 4.7 Service to the Customer (used to be Service to the Client)
  - 4.10 Improvement (totally new clause in the 2005 edition)

Changes in the Foreword

- **The Forewords in both editions are basically the same.**
- **The Second Edition added a new sentence to the Foreword's first paragraph**; *"In the field of conformity assessment, the ISO committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides."*

Changes in the Foreword

- **A new stand-alone sentence was added to the Second Edition Foreword which states:** "*It (ISO/IEC 17025) was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.*"
- **The second edition Foreword also states that** ***"****This second edition cancels and replaces the first edition (ISO/IEC 17025:1999), which has been technically revised."*

Changes in the Introduction

- **The Introduction** of the Second Edition added one new paragraph and significantly modified another paragraph from the First Edition.
- **The new paragraph states** *"The first edition referred to ISO 9001:2004 and ISO 9002:1994. These standards have been superseded by ISO 9001:2000, which made an alignment of ISO/IEC 17025 necessary. In this second edition, clauses have been amended or added only when considered necessary in the light of ISO 9001:2000."*

Changes in the Introduction

- **The significantly modified paragraph states** *"Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate the competence of the laboratory to produce* ***technically valid data and results****. Nor does demonstrated conformity to this International Standard imply conformity of the quality management system within which the laboratory operates to all the requirements of ISO 9001."*

Changes in Scope

- **1.4** This International Standard is for use by laboratories in developing their ***management system for quality, administrative and technical operations***. Laboratory ***customers***, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ***This International Standard is not intended to be used as the basis for certification of laboratories.***

Changes in Scope

- **1.4 - Two new Notes were added:**
  - *NOTE 1 The term '**management system**' in this International Standard means the quality, administrative and technical systems that govern the operations of the laboratory.*
  - *NOTE 2 **Certification** of a management system is sometimes also called **registration.***

Changes in Scope

- **Clause 1.6 had major changes made to it; it now reads:**
- "If testing and calibration laboratories comply with the requirements of this International Standard, they will operate a quality ***management*** system for their testing and calibration activities that also meets the ***principles of ISO 9001***. Annex A provides nominal cross-references between this International Standard and ISO 9001. ***This International Standard*** covers technical competence requirements that are not covered by ***ISO 9001."***

Changes in Scope

- **Notes 1 and 2 of Clause 1.6**
- **Substituted the new** *ISO/IEC 17011 – Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*
- **for the superseded** *ISO/IEC Guide 58.*

Changes in Scope

- **1.6-NOTE 1 It might be necessary to explain or interpret certain requirements in this International Standard to ensure that the requirements are applied in a consistent manner. Guidance for establishing applications for specific fields, especially for accreditation bodies (***see ISO/IEC 17011***) is given in annex B.**

- **1.6-NOTE 2 If a laboratory wishes accreditation for part or all of its testing and calibration activities, it should select an accreditation body that operates in accordance with** *ISO/IEC 17011.*

Changes in Normative References

- **The first paragraph of Clause 2 changed to:**
- "*The following referenced documents are indispensable for the application of this document.*
- *For dated references, only the edition cited applies.*
- *For undated references, the latest edition of the referenced document (including any amendments) applies."*

Changes in Normative References

- **The documents referenced include the new** *ISO/IEC 17000 - Conformity Assessment – Vocabulary and General Principles* **and the carry-over document** *VIM – International Vocabulary of Basic and General Terms in Metrology***.**
- **The second edition deleted** ISO 9001:1994**,** ISO 9002:1994, and ISO/IEC Guide 2 **from the normative references.**

Changes in Terms and Definitions

- **In this short Clause,**
- **the second edition substituted:**
- ***ISO/IEC 17000*** **for ISO/IEC Guide 2**
- ***ISO 9000*** **for ISO 8402**
- **in the Clause's one sentence and its accompanying Note.**

Changes in Management Requirements

- **Clause 4.1.2 changed by substituting "*customer*" for the word "client."**
- **The Clause now reads:**
- "It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the ***customer,*** the regulatory authorities or organizations providing recognition."

Changes in Management Requirements.

- **Clause 4.1.5 a) changed and added a number of words. It now reads:**
- "(The laboratory shall) a) have managerial and technical personnel ***who, irrespective of other responsibilities***, have the authority and resources needed to carry out their duties, ***including the implementation, maintenance and improvement of the management system***, and to identify the occurrence of departures from the ***management system*** or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);"

Changes in Management Requirements.

- **Clause 4.1.5 c) changed** “clients’” **to** “*customers*’.”
- **Clause 4.1.5 i) changed** “quality system’ **to** “*management system*.”
- **Clause 4.1.5 k) is all new and says** “(the laboratory shall) *ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.”*

Changes in Management Requirements.

- **Clause 4.1.6 is new and it states**
- **“***Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.”*

Changes in Management Requirements.

- ***4.2 MANAGEMENT SYSTEM***
- *The title of this Clause changed from Quality System to* ***Management System.***
- *In Clause 4.2.1, the phrase "quality system" was replaced by "****management system****."*

Changes in Management Requirements.

- The opening paragraph in 4.2.2 was rewritten to read:
- "The laboratory's ***management system*** policies ***related to quality, including a quality policy statement,*** shall be defined in a quality manual (however named). The overall objectives shall be ***established, and shall be reviewed during management review***. The quality policy statement shall be issued under the authority of ***top management***. It shall include at least the following: "

Changes in Management Requirements.

- Clause 4.2.2 c) formerly read “the objectives of the quality system” and now it reads “***the purpose of the management system related to quality.”***
- Clause 4.2.2 e) in the first edition read “**the laboratory management’s commitment to compliance with this International Standard**;” the second edition adds the following words to the original phrase, “***and to continually improve the effectiveness of the management system.”***
- The Note after 4.2.2 e) changed the phrase “clients’ requirements” to “***customers’*** requirements.”

Changes in Management Requirements.

- **Clause 4.2.3 is new and it says "***Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.*"
- **Clause 4.2.4 is also new and it states "***Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.*"

Changes in Management Requirements.

- **Clause 4.2.5** is the first edition's clause 4.2.3 with the term "quality system" replaced with "***management system***."
- **Clause 4.2.6** is the first edition's clause 4.2.4 and it reads "*The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the Quality Manual."*

Changes in Management Requirements.

- **Clause 4.2.7 in the second edition is new and it says**
- *"Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented."*

Changes in Management Requirements.

- **4.3 DOCUMENT CONTROL**
- **In Clause 4.3.1,** the second edition replaces the words “quality system” with the words “***management system*.”**
- Also, the last sentence in Note 2 is changed from “The control of records is covered in 4.12” to “The control of records is covered in ***4.13***.”

Changes in Management Requirements.

- **Clause 4.3.2 is Document approval and issue;**
- **The first sentence in clause 4.3.2.1 was changed from "**All documents issued by personnel in the laboratory as part of the *quality system* shall be reviewed and approved for use by authorizing personnel prior to issue**" to "**All documents issued by personnel in the laboratory as part of the ***management system*** shall be reviewed and approved for use by authorizing personnel prior to issue."

Changes in Management Requirements.

- **Clause 4.3.2.3 changed the first sentence from**
- **“***Quality system* documents generated by the laboratory shall be uniquely identified**” to**
- **“*Management system*** documents generated by the laboratory shall be uniquely identified.”

Changes in Management Requirements.

- **4.4 REVIEW OF REQUESTS, TENDERS AND CONTRACTS**
- **Clause 4.4.1 c) now reads** "the appropriate test and/or calibration method is selected and is capable of meeting the ***customers'*** requirements (see 5.4.2)"
- **The next paragraph now reads** "Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and to the ***customer.***"

Changes in Management Requirements.

- **In Note 1 of 4.4.1; the sentence "**For internal *clients*, reviews of requests, tenders and contracts can be performed in a simplified way**" was changed to read "**For internal ***customers,*** etc**."**
- **Note 3 of 4.4.1 was changed to read "**A contract may be any written or oral agreement to provide a ***customer*** with testing and/or calibration services" where ***customer*** was substituted for *client*.

Changes in Management Requirements.

- **Clause 4.4.2 was changed so it says** **“**Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a ***customer*** relating to the ***customer’s*** requirements or the results of the work during the period of execution of the contract**.”**
- This same substitution of ***customer*** for *client* occurred one additional time in the Note following 4.4.2 and in 4.4.4

Changes in Management Requirements.

- **4.5 Subcontracting of Tests and Calibrations**
- **Clause 4.5.2 in Edition 2 now reads** **“**The laboratory shall advise the ***customer*** of the arrangement in writing and, when appropriate, gain the approval of the ***customer,*** preferably in writing.”

Changes in Management Requirements.

- **Edition 2 of 17025 modifies Clause 4.5.3 to read**
- "The laboratory is responsible to the ***customer*** for the subcontractor's work, except in the case where the ***customer*** or a regulatory authority specifies which subcontractor is to be used."

Changes in Management Requirements.

- **4.6 Purchasing Services and Supplies**
- **Only one change was made to 4.6; the Note in 4.6.3 was changed to read** **“**The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the ***management system*** standard under which they were made.”

Changes in Management Requirements.

- **4.7 Service to the Customer**
- **The main title of this clause was changed from "Service to the *Client***
- **Clause 4.7.1 is new and it states "***The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers."*

Changes in Management Requirements.

- **4.7 Service to the Customer**
- **Clause 4.7.1** - Notes 1 and 2 remain the same from Edition 1 to Edition 2 except the word ***customer*** is substituted for the word client a number of times.
- **Clause 4.7.2 is new and it says "***The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service."*

Changes in Management Requirements.

- **4.7 Service to the Customer**
- The Note following 4.7.2 is **new** and it states
- "*Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.*"

Changes in Management Requirements.

- **4.8 Complaints**
- **This two-sentence clause was changed to read**
- "The laboratory shall have a policy and procedure for the resolution of complaints received from ***customers*** or other parties. Records shall be maintained or all complaints and of the investigations and corrective actions taken by the laboratory (see also ***4.11)***.

Changes in Management Requirements.

- **4.9 Control of Nonconforming Testing and/or Calibration Work**
- **In clause 4.9.1**, the term ***customer*** was substituted for the word “client” twice. Also, in the Note following 4.9.1, the expression ***management system*** was substituted for “quality system” two times.
- **In clause 4.9.2**, the reference to clause 4.10 was changed to ***4.11*** to reflect the numbering change in the second edition.

Changes in Management Requirements.

- **4.10 Improvement**
- This is an entirely **new** clause in the second edition.
- **It is one sentence that states** "*The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.*"

Changes in Management Requirements.

- **4.11 Corrective Action**
- This clause stayed primarily the same; the term ***management system*** was substituted for *quality system* twice and the word ***customer*** was substituted for *client* twice.
- In addition, a reference to clause 4.13 in 4.10.5 (Additional audits) in Edition 1 had to be changed to clause ***4.14*** in 4.11.5 (Additional audits) in Edition 2.

Clarification/Conformance. etc.

- **4.12 Preventive Action**
- **4.12.1** Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. ***When improvement opportunities*** are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

Changes in Management Requirements.

4.13 Control of Records

- No changes were made to this clause

Changes in Management Requirements.

- **4.14 Internal Audits**
- The term ***management system*** was substituted for *quality system* twice in 4.14.1.
- Also, in 4.14.2, the term ***customer*** was substituted for *client* one time.

Changes in Management Requirements.

- **4.15 Management Review**
- **The first sentence in 4.15.1 reads** "In accordance with a predetermined schedule and procedure, the laboratory's ***top*** management shall periodically conduct a review of the laboratory's ***management system*** and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements."
- In the list of items that the management review should consider, the phrase ***customer feedback*** replaced the phrase *client feedback* from Edition 1 and the phrase ***recommendations for improvement*** is entirely new to Edition 2.

Changes in Technical Requirements.

- **5 TECHNICAL REQUIREMENTS**
  - **5.1 GENERAL**
- **No changes were made to this major clause in 17025 in the second edition.**

Changes in Technical Requirements.

- **5.2 PERSONNEL**
- **In clause 5.2.1, Note 1 had a small change from *client* to *customer*; so it now reads**
- **“**In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the ***customer***.”

Changes in Technical Requirements.

- **5.2 PERSONNEL**

5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. ***The effectiveness of the training actions taken shall be evaluated.***

Changes in Technical Requirements.

- **5.3 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS**
- No changes were made to this major clause in 17025.

Changes in Technical Requirements.

- **5.4 TEST AND CALIBRATION METHODS AND METHOD VALIDATION**
- **In clause 5.4.1 – General,** the last sentence in the second paragraph was changed to read:
- **“**Deviation from test and calibration records shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the ***customer*****.”**
- **In clause 5.4.2 – Selection of methods**, the word ***customer*** is swapped with the word *client* five times.

Changes in Technical Requirements.

- **5.4 TEST AND CALIBRATION METHODS AND METHOD VALIDATION**
- **No changes were made to Clause 5.4.3 – Laboratory-developed methods.**
- **Clause 5.4.4 – Non-standard methods;** the first sentence was changed to read:
  - **“**When; it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the ***customer*** and shall include a clear specification of the ***customer’s*** requirements and the purpose of the test and/or calibration.”

Changes in Technical Requirements.

- **5.4 TEST AND CALIBRATION METHODS AND METHOD VALIDATION**
- **In Clause 5.4.5 – Validation of records,** the word ***customer*** is substituted for client in two locations.
- The first time it occurs is in the first paragraph of 5.4.5.3 and the second time it occurs is in Note 2 of 5.4.5.3.
- **In Clause 5.4.6 – Estimation of uncertainty of measurement;** the word ***customer*** is swapped for the word *client* in Note 1 of 5.4.6.2.

Changes in Technical Requirements.

- **5.5 EQUIPMENT**
- No changes were made to this major clause of 17025.

- **5.6 MEASUREMENT TRACEABILITY**
- No changes were made to this major clause of 17025.

Changes in Technical Requirements.

- **5.7 SAMPLING**
- **Clause 5.7.2 was revised to read** "Where the ***customer*** requires deviations, additions or exclusion from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel."

Changes in Technical Requirements.

- **5.8 HANDLING OF TEST AND CALIBRATION ITEMS**
- The word ***customer*** is substituted for *client* in 5.8.1 and 5.8.3.
- **Clause 5.8.1 in Edition 2 reads** "The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interest of the laboratory and the ***customer*****.**

Changes in Technical Requirements.

- **5.8 HANDLING OF TEST AND CALIBRATION ITEMS**
- **Clause 5.8.3 in Edition 2 of 17025** reads "Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the ***customer*** for further instructions before proceeding and shall record the discussion."

Changes in Technical Requirements.

- **5.9 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS**
- **Clause 5.9.1** is a new clause number that contains all the information contained in clause 5.9 of the first edition**.**
- **Clause 5.9.2 is all NEW to edition 2 and it says** "*Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported."*

Changes in Technical Requirements.

- **5.10 REPORTING THE RESULTS**

- **Clause 5.10.1 – General** was revised in the second edition to include the word ***customer*** in four different locations, thus, the word *client* was deleted and the word ***customer*** inserted in its place.

- **Clause 5.10.2 – Test Reports and Calibration Certificates, item d) reads** "the name and address of the ***customer***."

Changes in Technical Requirements.

- **5.10 REPORTING THE RESULTS**
- **Clause 5.10.3 – Test Reports** has in its clause 5.10.3.1 c) the phrase "***customer's* instructions"** and 5.10.3.1 e) the statement "additional information which may be required by specific methods, ***customers* or groups of *customers*.**"
- **Clause 5.10.4 – Calibration Certificates**, under clause 5.10.4.4, we have the following words: "A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the ***customer*.** This requirement may be superseded by legal regulations."

Changes in Technical Requirements.

- **5.10 REPORTING THE RESULTS**
- **Clause 5.10.5 – Opinions and Interpretations**
- We have in Note 3 the following:
- “In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the ***customer***. Such dialogue should be written down.”

17025:1999 versus 2005

- **Remember, the two-year transition period for the 2005 version started on May 12, 2005!**
- **The End**
- **Thank You!**